SUMMARY OF SAFETY AND EFFECTIVENESS

Simplici-T™ Annuloplasty System

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and CFR 807.92.

I SUBMITTER INFORMATION

Company Name:	Medtronic Heart Valves (Medtronic)
Company Address:	8299 Central Avenue N.E. Minneapolis, MN 55432
Company Phone:	(763) 514-6600
Company Facsimile:	(763) 514-6775
Contact Person:	Phil Neururer Regulatory Affairs Specialist
Date Summary Prepared:	October 21, 2005

II DEVICE IDENTIFICATION

Trade/Proprietary Name:	Simplici-T™ Annuloplasty System [Model 670]
21 CFR Reference:	870.3800
21 CFR Common Name:	Ring, Annuloplasty
Classification:	Class II
Panel:	CV (74) KRH

III IDENTIFICATION OF PREDICATE DEVICE

Device	Model #	FDA Clearance
Duran Band	H607H)	K032810
Duran Ring/Band	610R & 610B	same
Duran AnCore Ring/Band	620R & 620B	same
Duran AnCore Ring/Band with Chordal Guide	620R & 620B	Same

Cleared: December 5, 2003

IV DEVICE DESCRIPTION

The Simplici-T™ Annuloplasty System is a single use, permanent, flexible, implantable device intended for the repair of a patient's mitral and tricuspid valves.

The Simplici-T™ Annuloplasty Band is a 100 mm long band, constructed from a double velour polyester fabric wrapped around a small radiopaque silicone marker strip. Two locking running stitches run the entire 100mm band length creating a flat, low profile. A whipstitch on the side closes the band together. Implantation of the band is aided with the disposable band holder. The band is released from the holder by depressing the thumb trigger found on the handle of the holder. By depressing the thumb trigger, the holder bottom fingers push the band off of pins attached to the holder top. The device is sterilized by Steam Sterilization and has a One-year shelf life. The device is packaged on a holder in double aseptic pouches and shipped within a shelf-carton that includes instructions for use and product traceability labels.

V DESCRIPTION OF INTENDED USE

The Simplici-T™ Annuloplasty System, Model 670 is indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves. Appropriate repair and annular remodeling may correct combined valvular insufficiency and stenosis.

VI SUBSTANTIAL EQUIVALENCE

The Duran Product Family and the modified Simplici-T™ Annuloplasty System have the same fundamental scientific technology and intended use as the predicate device.

VII PERFORMANCE DATA

The Simplici-T™ Annuloplasty System was subjected to verification and validation studies. The verification/validation studies demonstrate that the modifications to the predicated device are appropriate and do not affect the intended use or performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2006

Medtronic, Inc.
c/o Mr. Phil Neururer
Regulatory Affairs Specialist
8299 Central Avenue NE
Minneapolsi, MN 55432-3576

Re: K052970
Simplici-T™ Annuloplasty System (Model 670)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (Two)
Product Code: KRH
Dated: December 13, 2005
Received: December 14, 2005

Dear Mr. Neururer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052970

510(k) Number (if known): K05 2 9 7 0

Device Name: Simplici-T™ Annuloplasty System [Model 670]

Indications for Use:

The Simplici-T™ Annuloplasty System is indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves. Appropriate repair and annular remodeling may correct combined valvular insufficiency and stenosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

Per 21 CFR 801.109

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052970